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Section 5. 510(k) Summary

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Trade Name: Leica FL800

Common Name: Fluorescent Angiographic System and/or Surgical Microscope

Classification Name: 21 CFR 892.1600 and/or 878.4700

1. **The legally marketed device to which Leica Microsystems is claiming equivalence:**

Novadaq SPY Intra-operative Imaging System (K042961)

2. **Description of the Leica FL800:**

Summary: The Leica FL800 device is a surgical microscope accessory used for viewing intra-operative blood flow in the cerebral vascular area. It allows the surgical microscope to produce excitation light and resolve fluorescence light from the fluorescent agent ICG.

A. Design Configuration

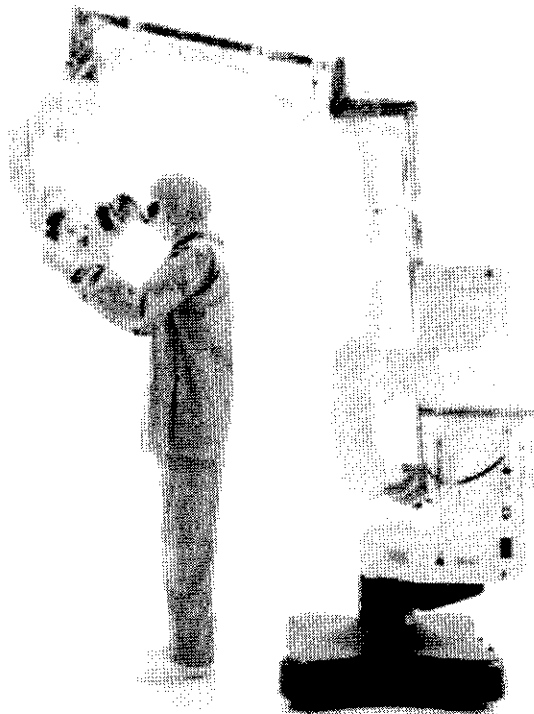
The Leica FL800 is an accessory to the Leica M520 OH3 Neurosurgical Microscope. The Leica FL800 is part of a surgical microscope system, which is comprised of five components, as listed below:

- i. Standard Leica M520 OH3 Microscope (Class I exempt)
- ii. Sony XC-E150 NIR (near infra-red) camera (part of Leica FL800 upgrade)
- iii. Leica Dual CCD Surgical Microscope Camera Adapter (part of Leica FL800 upgrade)
- iv. Leica modification of standard 300 Watt Xe light source (part of

- Leica FL800 upgrade)
- v. Leica FL800 electronic control unit (part of Leica FL800 upgrade)
- vi. ICG Fluorescence Dye (labeled for use with the Leica FL800)

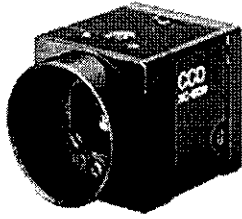
Each component is briefly described below. The M520 OH3 brochure is included as Annex 1, and the Leica FL800 proposed brochure is included as Annex 2.

i. **Standard M520 OH3 Microscope** – This microscope is Leica's high-end surgical microscope and is presently a Class I exempt device (Sec. 878.4700, surgical microscope and accessories). It is a fully balanced microscope that offers configurations for craniotomy, spine and other forms of neurosurgery. (Annex 1 contains the OH3 commercial brochure.)



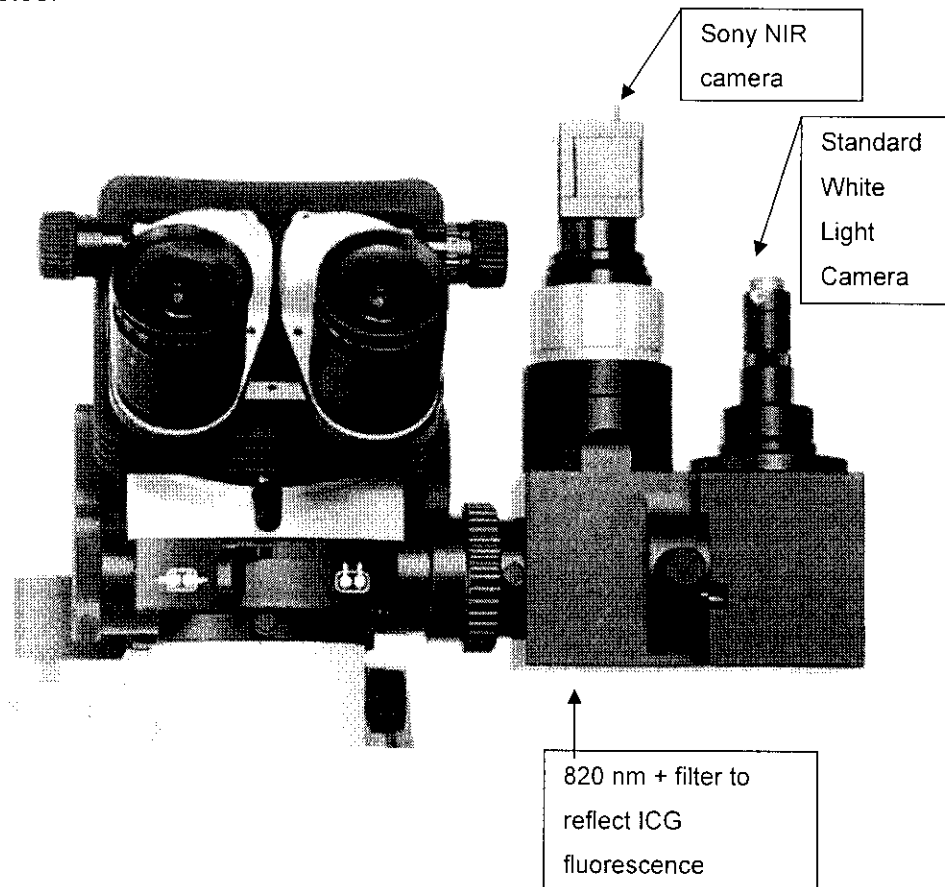
ii. **Leica FL800 Component: Sony XCE 150 NIR (near infra-red) Camera –**

This camera is an off-the-shelf Sony CCD designed principally for NIR imaging. Leica does not modify this camera in any way.



iii. **Leica FL800 Component: Dual CCD Surgical Microscope Camera Adapter –**

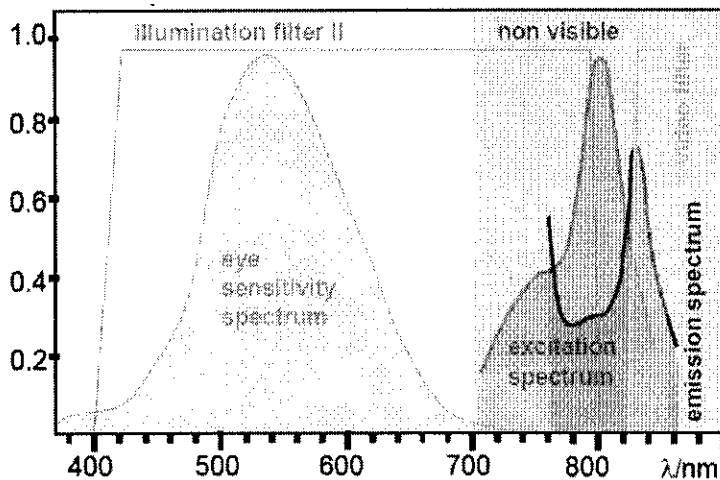
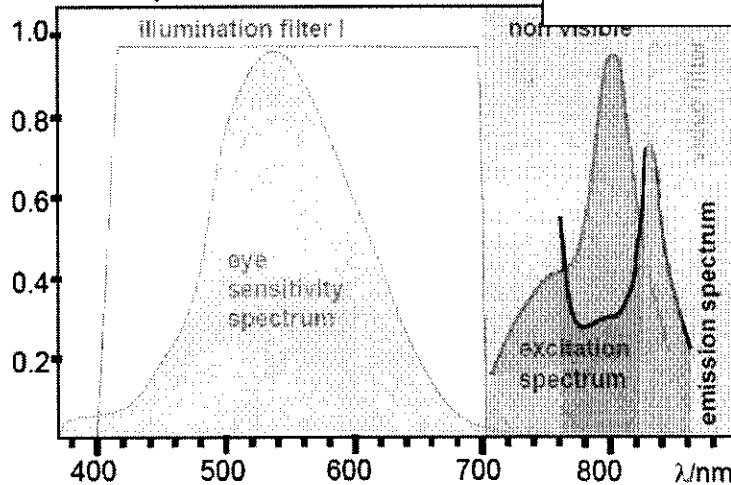
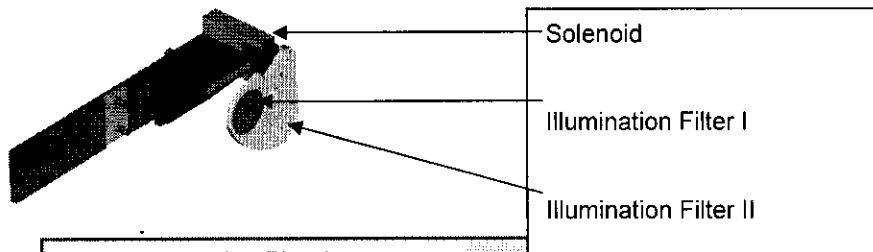
The dual camera adapter was built specifically by Leica Heerbrugg Switzerland for the Leica FL800. It consists of two camera ports and one 820 nm plus reflective filter. The first camera is the NIR Sony camera mentioned above, and the second camera is a standard medical approved white light imaging camera of the customer's choice.



iv. **Leica FL800 Component: Modified Xe Light Source –**

The standard M520 OH3 uses a 300-watt Xe light source. As a normal standard of precaution, Leica filters all light higher than 720 nm. For the Leica

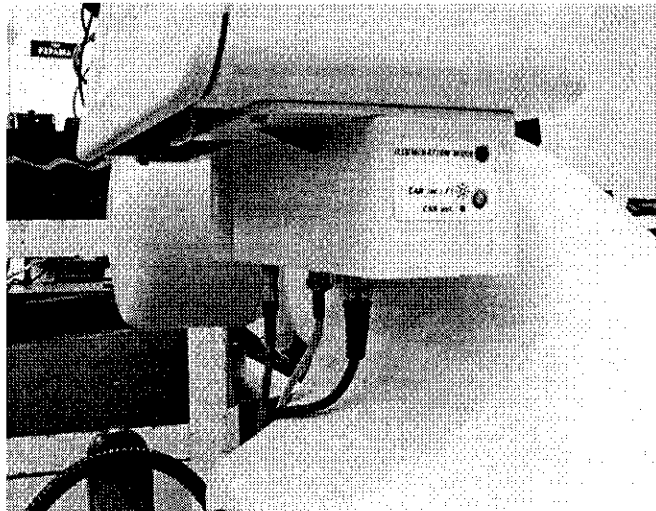
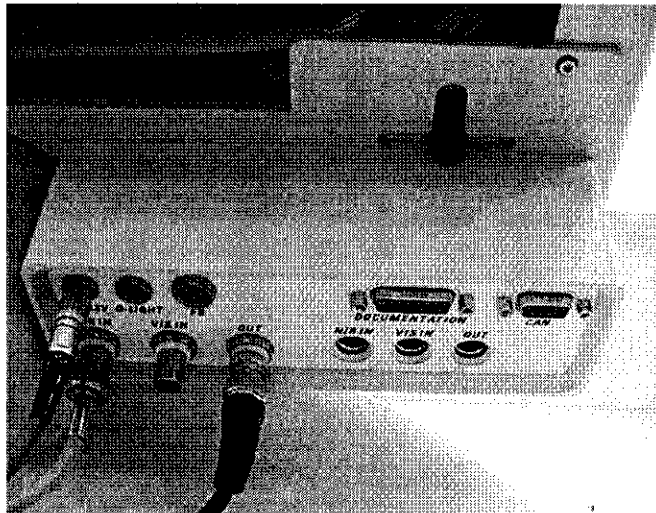
FL800, this filtering is modified to permit replacing the normal filter (Filter 1) with Filter 2, which allows a greater spectrum of Xe light (including the 805 nm) to flow to the surgical site. Filter 2 does not allow light through in the fluorescence range of 835 nm, as this light would wash out the fluorescence of the ICG. See charts below for spectra output of normal surgical light (Filter 1) and white light with 805 nm excitation allowed through.



v. **Leica FL800 Component: Electronic Control Unit –**

The existing M520 OH3 Microscope has an additional control unit that allows the customer to simultaneously perform the following functions by using a single button:

- a. Exchange Filter 1 for Filter 2, allowing 805 excitation light.
- b. Switch video output from white light to NIR light.
- c. Allow optional injection of image to eyepiece and customer's video recorder to begin recording.
- d. The system will reset to the normal (Filter 1 in and white light video on) in three minutes, should surgeon forget to turn the unit off after the ICG has flowed.



vi. **Leica FL800 Component: Fluorescent Agent – Akorn ICG (Indocyanine - Green) –**

The Leica FL800 is labeled for use with Akorn Inc.'s Indocyanine-Green (ICG), a green dye that temporarily binds with serum albumin, its fluorescent agent. When exposed to 805 nm NIR light, this agent causes fluorescence at 835 nm. The system's NIR camera captures the fluorescence, and can thereby image blood coursing through the circulatory system. Akorn's ICG is FDA-approved and indicated for "determining cardiac output, hepatic function and liver blood flow, and for ophthalmic angiography."

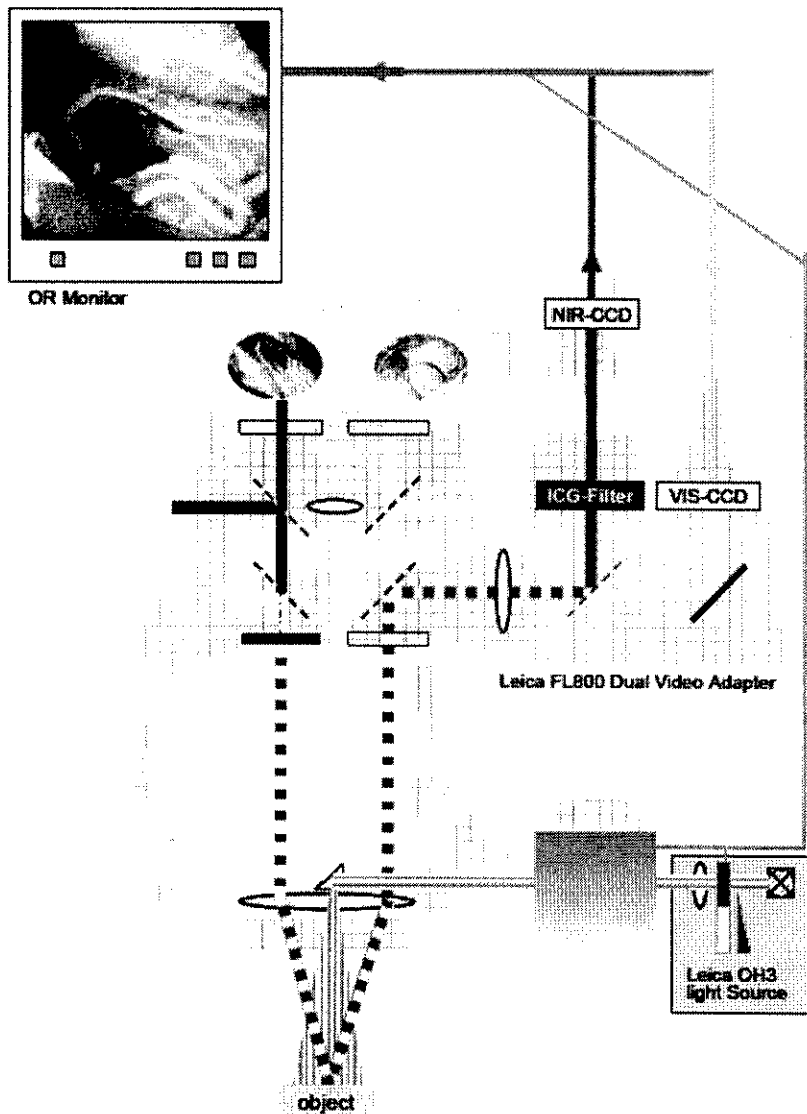
The use of ICG for viewing intra-operative blood flow in the cerebral vascular area in the present instance presents no material distinction from its approved uses in the eye, heart, and liver. When, for example, ICG is used for imaging vasculature in the back of the eye, it is injected intravenously. The eye and brain share the same source of blood supply – the carotid arteries. Because the dye disperses throughout the circulatory system rapidly upon injection, it will travel to the brain just as it travels to the vasculature actually observed via angiography in the eye. Consequently, approved use of ICG for viewing the vasculature involves the dispersal of ICG into the cerebral vasculature as well.

Note: The Leica FL800 uses the ICG in the identical dose and route of administration as the Akorn product is labeled. The Akorn product has been used in this manner for forty years. Each time ICG was used for retinal angiography in the past forty years, the ICG drug flowed through the cerebral vascular area. The Leica FL800 does not change this in any way. The Leica FL800 allows the surgeon to see the ICG as it is seen in retinal angiography and by cardiac surgeons using the Novadaq SPY device.

A copy of the Akorn ICG drug insert is included as Annex 4.



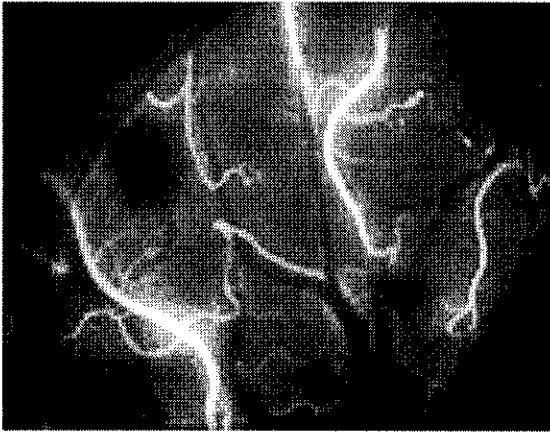
Summary of the Functional Components of the Leica FL800:



B. Principles of Clinical Operation

The system starts with a standard M520 OH3 Surgical Microscope, which has been sold by Leica in the United States for several years (Annex 1 for commercial brochure). The M520 OH3, as noted, is a Class I exempt device (Sec. 878.4700, Surgical microscope and accessories). The Leica FL800 is added to the M520 OH3 unit by a Leica service technician and it is ready to be used. The dual CCD camera adapter and additional NIR camera are the only easily recognized changes.

When a surgeon wishes to use the Leica FL800, he/she pushes one button. This one button exchanges Filter 1 for Filter 2, allowing the 805 nm light through and switches the video output from white light to NIR. The surgeon then has the ICG injected intravenously through a central venous line according to the drug's already existing labeling. The bolus of the ICG will now flow through three phases: arterial, capillary, and venous. The three images below represent the three phases:



Bolus passage
after 2 seconds:
arterial view



Bolus passage
after 5 seconds:
capillary view



Bolus passage
after 9 seconds:
venous view

At the end of the venous view, the surgeon can elect to turn the Leica FL800 off or it will turn off automatically after three minutes. When turned off, the video output will return to white light from NIR light.

3. Intended use of the Leica FL800.

a. The Leica FL800 is attended to allow neurosurgeons to view blood flow. It will be used in cranial surgery in assessing vessels, which may have any of the following conditions:

1. Before and after by-pass surgery
2. Before and after aneurysm surgery
3. Before and after AV malformation surgery
4. Before tumor surgery to evaluate blood flow

b. Patient population will be all patients undergoing one of the above neurosurgical procedures.

c. The Novadaq SPY device is used in the identical way and for the identical purpose of visualizing the blood flow through vessels. The Leica FL800 will use a before and after image like the Novadaq Spy to view the change that the surgical procedure has had on blood flow.

4. Technological Characteristics compared to the Novadaq SPY device.

The Leica FL800 also possesses the same or similar technological characteristics as the predicate devices. As noted, the Leica FL800 is the same device as the exempt M520 OH3 with the addition of a module that enables viewing of blood flow. The Novadaq SPY employs a similar system for visual assessment of the coronary vasculature that comprises the Leica FL800 module. Importantly, like the instant device, the Novadaq SPY uses ICG as its fluorescent agent, an 805 nm light source for excitation of the ICG, and an 835 nm fluorescence camera for viewing intra-operative blood flow. Minor technological differences do exist. The Novadaq SPY uses a laser diode as its light source for ICG excitation, whereas the Leica FL800 module uses a specially filtered 300-watt Xenon light source. This minor difference does not raise any new questions regarding safety or effectiveness. The Leica FL800 produces roughly the same energy as the laser diode in the 805 nm range. Furthermore, the Leica FL800's energy level is below ANSI standards, as explained below in Section 15. The white light of the microscope continues to run, allowing the surgeon to visualize normally through the microscope even during NIR imaging. This circumstance is not present in the use of the Novadaq laser diode light source, as the Novadaq has no ability to image normal white light. In the Leica FL800, the white light is relied on for observing through the microscope as discussed above, and white light imaging is critical to the surgeon for the indicated use of the standard exempt M520 OH3 microscope.

Because the Leica FL800 possesses the same or similar intended use, indications, and technological characteristics as the identified predicate device, with no new questions of safety or effectiveness present, the company submits that the device can be found substantially equivalent.

5. Non-clinical Performance Data - Leica tests each Leica FL800 with a Pulsion Phantom that is specifically designed to test ICG fluorescence camera systems. This test has proven reliable, but will be reviewed to insure it is the best quality standard for this system. The test has been performed for many years in the retinal angiogram field.

6. Clinical Validation –

a. Validation: A validation of concept was performed in Dresden, Germany in September 2005. The CD included in Annex 5 shows one of these cases, and is labeled "fluorescence Vas OH3 Dres." Professor Dr. med G. Shackert, a member of the medical faculty Carl Gustav Carur, Technical University Dresden, Germany performed the test. Although all tests were successful, a number of issues were discovered, including the need for NIR light and white light to reach a closer focus plane. In addition, there was the need to automatically switch video and other user functions to make the unit more OR friendly.

b. Clinical Test: From January to April 2006, the University of Illinois – Chicago had the Leica FL800 installed on a OH3 M520 Microscope in their OR under an IRB. The objective of the study was to examine the use of ICG fluorescence in cerebral vascular surgery. In addition, the University wanted to determine the function of the Leica FL800 and its usefulness in neurosurgery. Five of these cases are provided on the CD included in Annex 5.

c. Methodology: An IRB form was filed with the University of Illinois IRB Committee and approved. Patients were given consent forms and procedures were performed based on the normal flow of patients to the OR. All cases were performed under white light until they got to the point of cerebral vascular interest. At that point, an ICG Fluorescence baseline video was taken. This image was recorded on a digital recording station. After the procedure was performed (for example, STA-MCA), an additional ICG fluorescence was performed and recorded. In each bypass case, the results were followed up with a sonogram that confirmed that the qualitative ICG fluorescence was correct in terms of the sonogram. Each patient was followed up with a postoperative angiography. Two levels of optical splitters were tried one allowing only 20% of the NIR and the other allowing 40% of NIR to be sent to the Sony NIR camera.

d. Results: In the 18 cases, the Leica FL800 performed well. However, in the 7 cases performed under 20% NIR, the signal was too weak for consistent excellent quality. In the 11 cases performed under 40% NIR, the results were all excellent; and therefore, the Leica FL800 specification and test parameter was fixed at "NIR signal to camera must exceed 40% of available NIR light."

e. Conclusion of Clinical Validation: The Leica FL800 proved to be successful in the visualization of blood flow. On two occasions, the surgeon chose to revise his anastomosis based on the insufficient patency of his bypass. In all other bypass cases, the Leica FL800 confirmed that the bypass was patent as

desired. In one aneurysm case, the Leica FL800 clearly showed that the clipping was not optimal and needed revision. In the other aneurysm cases, the Leica FL800 confirmed a successful clip placement.

7. Conclusion of Clinical and Non-clinical Validation Compared to Novadaq SPY - The conclusions from the clinical and non-clinical tests discussed above demonstrate that the Leica FL800 is as safe, as effective, and performs as well as the Novadaq SPY device.



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Rockville MD 20850

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Re: K061871

Trade/Device Name: Leica FL800
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: IZI, EPT
Dated: June 26, 2006
Received: July 3, 2006

Dear Mr. Sturgis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4. Indications for Use

510(k) Number (if known): K 061871

Device Name: **Leica FL800**

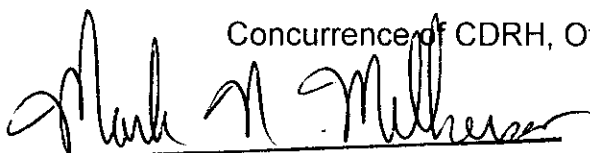
Indications for Use: The Leica FL800 is a surgical microscope accessory used in viewing intra-operative blood flow in the cerebral vascular area.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF
NEEDED)



Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of _____

(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K 061871 4-1